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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,713	01/25/2006	Dieter Scheller	6102-000008/US/NP	7929

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EXAMINER	
RAMACHANDRAN, UMAMAHESWARI	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
12/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,713	SCHELLER ET AL.	
	Examiner	Art Unit	
	UMAMAHESWARI RAMACHANDRAN	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *16-77* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15 are cancelled. Claims 16-77 are pending.

Lack of Unity

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 16, 36, 68-77 are drawn to a therapeutic combination comprising a compound of formula (claim 16) with one or more additional active ingredient selected from antidepressants, antipsychotics, sedatives, anxiolytics, and or anti-migraine agents.

Group II claims 17-28, 30-57, 66, 67 are drawn to a method of depression comprising administering to the mammal a therapeutically effective amount of a compound of formula (claim 17) and an additional active ingredient antidepressant.

Group III, claims 17-34, 37-55, 58, 59, 66, 67 are drawn to a method of depression comprising administering to the mammal a therapeutically effective amount of a compound of formula (claim 17) and an additional active ingredient, antipsychotics.

Group IV, claims 17-34, 37-55, 60, 61, 66, 67 are drawn to a method of depression comprising administering to the mammal a therapeutically effective amount of a compound of formula (claim 17) and an additional active ingredient, sedatives.

Group V, claims 17-34, 37-55, 62, 63, 66, 67 are drawn to a method of depression comprising administering to the mammal a therapeutically effective amount of a compound of formula (claim 17) and an additional active ingredient, anxiolytics.

Group VI, claims 17-34, 37-55, 64-67 are drawn to a method of depression comprising administering to the mammal a therapeutically effective amount of a compound of formula (claim 17) and an additional active ingredient, anti-migraine agents.

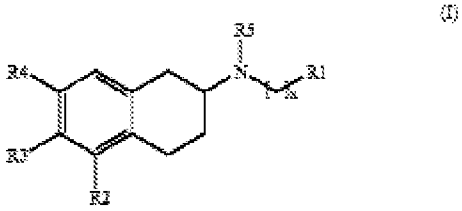
The inventions listed as Groups I – VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features.

An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

The expression “special technical features” is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any). Whether or not any particular technical feature makes a “contribution” over the

prior art, and therefore constitutes a “special technical feature”, should be considered with respect to novelty and inventive step.

The common technical feature in all the groups is a compound of formula given below. They are substituted 2-amino tetralin compounds.



. This element cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art.

Rimpler et al. (U.S. 2003/0166709) teaches a compound of the above said formula, Rotigotine (N-0923) as a potent and selective dopamine D2 agonist compound (see Abstract, p1, para 004). As a result, no special technical features exist among the different groups because the inventions in Groups I-VI fail to make a contribution over the prior art with respect to novelty or inventive step. In conclusion, there is lack of unity of inventions, and therefore restriction for examination purposes as indicated is proper.

If Applicant elects Groups I applicant is further required to elect a single disclosed species of the compound of formula I (example, rotigotine), elect a single disclosed species from one of the additional ingredients e.g antidepressants (as the species) from the list of antidepressants, antipsychotics, sedatives, anxiolytics or anti-migraine agents. In addition Applicants' are required to elect one subspecies (one single

compound) from the species election, for example, Citalopram as an antidepressant compound if antidepressant species are elected.

If Applicant elects Group II, applicant is further required to elect a single disclosed species of the compound of formula I (example, rotigotine), elect single species of depression e.g. somatogenic depression and also elect a species of the antidepressant compound such as Citalopram and a species of the affective disorder (claim 48).

If Applicant elects Group III, applicant is further required to elect a single disclosed species of the compound of formula I (example, rotigotine), elect single species of depression e.g. somatogenic depression and also elect a species of the antipsychotic compound such as promethazine and a species of the affective disorder (claim 48).

If Applicant elects Group IV, applicant is further required to elect a single disclosed species of the compound of formula I (example, rotigotine), elect single species of depression e.g. somatogenic depression and also elect a species of the sedative compound such as promethazine and a species of the affective disorder (claim 48).

If Applicant elects Group V, applicant is further required to elect a single disclosed species of the compound of formula I (example, rotigotine), elect single species of depression e.g. somatogenic depression and also elect a species of the anxiolytic compound such as fluspirilene and a species of the affective disorder (claim 48).

If Applicant elects Group VI, applicant is further required to elect a single disclosed species of the compound of formula I (example, rotigotine), elect single species of depression e.g. somatogenic depression and also elect a species of the anti-migraine compound such as acetylsalicylic acid and a species of the affective disorder (claim 48).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i). Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.1.43).

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Because the restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See MPEP § 812.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617